

VASCULAR-ACCESS SIMULATION SYSTEM
WITH SKIN-INTERACTION FEATURES

Statement of Related Cases

[0001] This case is related to U.S. Patent Applications S.N. _____ (Atty. Dkt. No. 115-002), S.N. _____ (Atty. Dkt. No. 115-003), S.N. _____ (Atty. Dkt. No. 115-004), and S.N. _____ (Atty. Dkt. No. 115-005), all of which are incorporated by reference herein.

Field of the Invention

[0002] The present invention relates generally to systems that simulate medical procedures for the purposes of training or accreditation. More particularly, the present invention relates to a system, apparatus and subsystems for simulating vascular-access procedures.

Background of the Invention

[0003] Medical practitioners, such as military medics, civilian emergency-medical personnel, nurses, and physicians, routinely perform vascular-access procedures (e.g., IV insertion, central venous-line placement, peripherally-inserted central catheter, etc.). It is desirable for a practitioner to be proficient at performing these procedures since the proficient practitioner is far less likely to injure a patient and is almost certain to reduce the patient's level of discomfort.

[0004] Becoming proficient in vascular-access procedures requires practice. In fact, the certification and re-certification requirements of some states mandate a minimal number of needle sticks, etc., per year per provider. Historically, medical practitioners practiced needle-based procedures on live volunteers. More recently, simulation techniques and devices have been developed to provide training in vascular-access procedures without the use of live volunteers. U.S. Pat. No. 6,470,302 ("the '302 patent") surveys the art of medical-simulation devices and also discloses a vascular-access simulation system.

[0005] The vascular-access simulation system that is disclosed in the '302 patent includes an "interface" device and a computer system. To practice a vascular-access procedure, a user manipulates an "instrument," referred to in the patent as a "catheter unit assembly," which extends from the device and serves as a catheter-needle. Potentiometers and encoders within the interface device track the

motion and position of the instrument and relay this information to the computer system. The computer system performs a simulation of the surface and subsurface anatomy of human skin, and determines the effect of the instrument's motion on the skin's anatomy. Simulated results are displayed by the computer system. Using the motion information from the interface device, the computer system also generates a control signal that controls a force-feedback system that is coupled to the instrument. The force-feedback system generates various resistive or reactive forces that are intended to simulate the forces that are experienced by a medical practitioner during an actual vascular-access procedure. The user senses these forces during manipulation of the instrument.

[0006] The system that is disclosed in the '302 patent has many shortcomings that substantially limit its utility as a training or accreditation tool. In particular, among other drawbacks, the system that is disclosed in the '302 patent provides only a limited ability to practice and realistically mimic certain skin-interaction techniques that are an important part of vascular-access procedures. These skin-interaction techniques include "palpation," "skin stretch," and "occlusion."

[0007] Palpation is a multi-purpose technique. It can be used by a practitioner to locate hidden veins. Veins might not be readily locatable due to the advanced age or poor physical condition of the patient, the procedure being performed, or due to other reasons. To palpate for hidden veins, the practitioner pats the skin. Palpation can also be used to obtain information about a candidate vein once it has been located. In particular, the practitioner can determine whether the candidate vein is sufficiently engorged. A practitioner can also determine, via palpation, whether a vein is sufficiently straight (at an intended insertion point) for catheterization. To palpate a vein to obtain this type of information, the practitioner moves one or two fingers lightly over the candidate vein.

[0008] Occlusion is a technique that is performed during catheterization. Specifically, a finger or thumb of the non-dominant hand is used to apply pressure on the catheter at the insertion point so that no blood leaks out of the hub of the catheter when the stylet is removed. To practice the third technique mentioned above—the skin-stretch technique—the thumb of the non-dominant hand pulls a patient's skin, rendering it taut. This reduces a patient's level of discomfort and anchors the vein so that it doesn't move during angiocatheter insertion.

[0009] Of these three skin-interaction techniques, only the "skin stretch" can be practiced using the device that is disclosed in the '302 patent. And the mechanism that is responsible for skin stretch has a limited ability to realistically simulate this procedure. In particular, the "skin" on which the skin stretch technique is practiced is a belt—a "mock" skin—that bears little resemblance to real skin. A resilient backing is disposed beneath the belt to simulate the resiliency of skin. (See, col. 10, lines 49+.) Furthermore, the module on which the skin-stretch technique is practiced resides within a casing that is attached to and separate from the housing in which the needle-insertion procedure is practiced. This structural arrangement does nothing to promote a user's "suspension of disbelief." That is, it is clear that the technique is being performed on a machine that is not the least bit suggestive of human anatomy.

[0010] The inability to practice and realistically simulate these skin-interaction techniques limits the utility of prior-art vascular-access simulation systems for use as a training or accreditation tool.

Summary

[0011] The illustrative embodiment of the present invention is a simulation system that provides realistic training and practice for vascular-access procedures without using human subjects. Unlike most prior-art simulation systems, some embodiments of the present system provide a realistic simulation of forces as well as an ability to practice several important skin-interaction techniques that are normally performed as a part of many vascular-access procedures.

[0012] In accordance with the illustrative embodiment, vascular-access simulator includes a data-processing system and an interface device, referred to herein as a "haptics device." The haptics device provides the physical interface for performing vascular-access procedures. More particularly, a user inserts a needle/catheter module into the haptics device and manipulates it to simulate needle insertion, cannulation, etc.

[0013] In accordance with the illustrative embodiment, the haptics device includes a palpation module. In some embodiments, the palpation module enables a user to perform two skin-interaction techniques: palpation and occlusion. With regard to the palpation technique, the palpation module advantageously provides

one or more of the following functions: enables a user to search for a vein; provides tactile feedback to user; and provides an indirect measure of palpation force.

[0014] Furthermore, in some embodiments of the palpation module, a vein that is tactiley discernable (*i.e.*, felt) by a user is not visually discernable by the user. Also, in some embodiments, the perceived "stiffness" of a vein, which is indicative of its degree of engorgement, is controllable. An illustrative structural configuration of the palpation module that provides the desired functionality and certain desirable characteristics is presented.

[0015] In some embodiments, the haptics device includes a skin-stretch module. The skin-stretch module enables a user to perform a skin-stretch technique that accompanies many vascular-access procedures. The skin-stretch module advantageously enables a user to stretch a pseudo skin, provides appropriate and realistic sensory feedback to the user, and quantifies the amount of skin stretch that has occurred.

[0016] Sensors within the haptics device monitor the motion and position of the needle/catheter module as well as the application of pressure, etc., and the movement of pseudo skin during the skin-interaction techniques. The sensors generate signals indicative of the monitored activity and transmit the signals to the data processing system.

[0017] The data processing system processes the information acquired by the sensors and, in conjunction with an anatomical model, determines the effect of a user's manipulations on the surface and subsurface features of the virtual body part on which the simulated vascular-access procedure is being performed. Results are displayed by the computer system. The results include, for example, a three-dimensional rendering of the body part of interest, a visual indication of the position of the needle/catheter relative to the body part, and a visual indication of how the needle/catheter affects that body part.

[0018] Using the information obtained from the sensors, the data processing system determines the various resistive forces that would arise from the user's manipulation of the needle/catheter assembly through the simulated anatomy. Based on this determination, the data processing system generates a control signal and transmits it to the haptics device. Responsive to the control signal, the haptics device generates an appropriate amount of resistance to movement of the needle/catheter assembly.

Brief Description of the Drawings

[0019] FIG. 1 depicts vascular-access simulation system 100 in accordance with the illustrative embodiment of the present invention.

[0020] FIG. 2 depicts functional elements of haptics device 102, which is a part of vascular-access simulation system 100.

[0021] FIG. 3 depicts a top view of haptics device 102.

[0022] FIG. 4A depicts an exploded view of a palpation assembly in accordance with the illustrative embodiment of the present invention.

[0023] FIG. 4B depicts a top view of a bottom plate of the palpation assembly of FIG. 4A.

[0024] FIG. 4C depicts a top view of a top plate of the palpation assembly of FIG. 4A.

[0025] FIG. 4D depicts a pseudo vein extending above the upper surface of the upper plate of the palpation assembly of FIG. 4A.

[0026] FIG. 4E depicts the pseudo vein flush with the upper surface of the upper plate of the palpation assembly of FIG. 4A.

[0027] FIG. 5A depicts a top view of a skin-stretch assembly in accordance with the illustrative embodiment of the present invention.

[0028] FIG. 5B depicts a side view of the skin-stretch assembly of FIG. 5A and showing the skin-stretch assembly disposed beneath pseudo skin.

[0029] FIG. 5C depicts a downward force being applied to the pseudo skin, which forces it into contact with a slide of a linear potentiometer.

[0030] FIG. 5D depicts a pulling force being applied to the pseudo skin, which causes the slide of the linear potentiometer to move, thereby tracking the stretch of the pseudo skin.

Detailed Description

[0031] The terms and phrases listed below are defined for use in this specification as follows:

[0032] “**End Effector**” means a device, tool or instrument for performing a task. The structure of an end effector depends on the intended task. For example,

in the illustrative embodiment, the end effector is intended to be used to simulate a vascular access procedure, and is therefore implemented as a catheter-needle module. Those skilled in the art will recognize that term "end effector" is borrowed from robotics, where it has a somewhat different definition: a device or tool connected to the end of a robot arm.

[0033] "**Imitation**" means an artificial likeness that is intended to be substantially similar to an item being imitated; a copy. For example, "imitation skin," which is used in conjunction with the illustrative embodiment of the present invention, is intended to mimic or copy real skin via appropriate selection of color, appearance, feel, and overall presentation.

[0034] "**Mock**" means "representative;" a stand-in for a genuine article, but not intended to be a copy or reproduction of the genuine article. A mock article will typically not promote a suspension of disbelief that the mock article is the genuine article. For example, "mock skin" is not intended to mimic real skin, and typically departs from the real thing in color, appearance, feel or overall presentation.

[0035] "**Pseudo**" is an inclusive term that means "imitation" or "mock." For example, pseudo skin is meant to encompass both imitation skin and mock skin.

[0036] "**Skin**" means genuine skin.

[0037] This *Detailed Description* continues with an overview of a vascular-access simulator in accordance with the illustrative embodiment. Following the overview, specific embodiments of several elements of the simulator are described in greater detail.

Overview

[0038] The illustrative embodiment of the present invention pertains to a simulation system that provides realistic training and practice for vascular-access procedures without using human subjects. As depicted in FIG. 1, vascular-access simulator 100 includes haptics device 102 and data-processing system 104.

[0039] Haptics device 102 provides the physical interface for performing any of several simulated vascular-access procedures (e.g., intravenous catheterization, central venous line placement, sternal intraosseous insertion, etc.).

[0040] The term "haptics" relates to touch (*i.e.*, the sense of touch). A fundamental function of haptics device 102, and indeed any haptics interface, is to

create a means for communication between users (*i.e.*, humans) and machines. This “communication” is possible since humans are capable of “mechanically” interfacing with their surroundings due, at least in part, to a sense of touch. This “sense of touch” includes sensations of pressure, texture, puncture, thermal properties, softness, wetness, friction-induced phenomena, adhesions, etc. Furthermore, humans also experience vibro-tactile sensations, which include the perception of oscillating objects in contact with the skin and kinesthetic perceptions (*i.e.*, awareness of one’s body state, including position, velocity, and forces supplied by the muscles). As will become clear later in this *Detailed Description*, our ability to perceive a variety of these sensations is exploited by haptics device **102**.

[0041] To the extent that some embodiments of simulator **100** are intended for use as a practice and training tool, it is advantageous for haptics device **102** to simulate vascular-access procedures as realistically as possible and provide a quantitative measure of the user’s performance of the simulated procedure. To this end, haptics device **102** possesses one or more of the following attributes, in addition to any others:

- It possesses sufficient degrees-of-freedom to simulate an actual vascular-access procedure.
- It offers the opportunity to perform all steps of a vascular-access procedure, including, for example, needle insertion, skin interactions (*e.g.*, palpation, skin stretch, *etc.*), catheter threading, *etc.*
- It generates appropriate skin- and venous-puncture forces.
- It measures or otherwise quantifies the effects of user actions on simulated anatomy.
- It generates appropriate haptic feedback (*i.e.*, feel) during skin-interaction steps.
- It is configured to provide ergonomically-correct hand position during simulated vascular-access procedures.
- It is small enough so that it can be positioned in front of a computer monitor so that the haptics device and the monitor are inline with a user’s forward-looking field of view.
- It is at least subtly suggestive of human anatomy and does not present any substantial departures therefrom so as to support a user’s ability to suspend disbelief during a simulated vascular-access procedure.

[0042] Data-processing system **104**, which includes processor **106**, monitor **108**, keyboard **110**, mouse **112**, and speakers **114**, supports the visual aspects of the simulation, among other functions. Processor **106** is a general-purpose processor that is capable of receiving and processing signals from haptics device **102**, running software for the visual portion of the vascular-access simulation including an anatomy simulator, running calibration software for calibrating the various sensing elements used in haptics device **102**, and sending control signals to haptics device **102** to support closed-loop force feedback, among other capabilities. Processor **106** comprises memory, in which the software described above is stored. In the illustrative embodiment, processor **106** is a personal computer.

[0043] Monitor **108** displays a rendering that is generated by processor **106**, in conjunction with the above-referenced software. The rendering, which in some embodiments is three-dimensional, is of a region of the body (e.g., isolated arm, thorax, neck, etc.) on which a simulated vascular-access procedure is being performed. The rendering advantageously depicts visual aspects such as, without limitation, the anatomical structures that underlie the skin, local deformation of the skin in response to simulated contact, and tracking of a "virtual" instrument (e.g., a needle, etc.) through anatomical structures that underlie the skin.

[0044] Haptics device **102** is now described in further detail. For pedagogical purposes, haptics device **102** is depicted in FIG. 2 as comprising several functional modules or elements. These include:

- End effector or needle/catheter module **218**;
- Pseudo skin **220**;
- Palpation module **222**;
- Skin-stretch module **224**;
- Needle-stick module **226**; and
- Electronics/communications interface **228**.

[0045] The functional elements of haptics device **102** listed above that relate to human anatomical features or are otherwise intended to generate resistive forces that would be sensed when penetrating such anatomical features (elements **222** – **228**) are advantageously contained within housing **216** or otherwise located "underneath" pseudo skin **220**. In an actual vascular-access procedure, the needle or catheter, of course, remains outside of the body until inserted during the procedure. Likewise, in accordance with the illustrative embodiment, the end

effector—needle/catheter module **218**—remains outside of housing **216** and above pseudo skin **220** until a portion of it is inserted during a simulated vascular-access procedure. In some embodiments, housing **216** is subtly shaped like a portion of a human arm, yet is nondescript enough to avoid creating a discontinuity between what is seen and what is felt.

[0046] Pseudo skin **220** is a membrane that is used in conjunction with the simulation of skin-interaction techniques, such as palpation, occlusion, and skin stretch techniques. Pseudo skin **220** is advantageously, but not necessarily, imitation skin (*i.e.*, skin-like in appearance). To that end, pseudo skin **220** should have any one of a number of natural flesh tones. In some embodiments, pseudo skin **220** is at least somewhat resilient to enable a user to perform skin-interaction techniques. In some embodiments, pseudo skin **220** comprises a thermoplastic elastomer such as Cawiton®, which is available from Wittenburg, B.V., Hoevelaken, Netherlands. The use of imitation skin, as opposed to mock skin, is desirable because it helps a user to “suspend disbelief,” which contributes to making simulator **100** more useful as a training tool.

[0047] As depicted in FIG. 3, pseudo skin **220** is accessed for skin-interaction techniques through openings **330** and **332** in housing **216**. Opening **330** defines palpation/occlusion region **331** (*i.e.*, the site at which palpation and occlusion techniques are performed) and opening **332** defines skin-stretch region **333** (*i.e.*, the site at which the skin-stretch technique is performed) and includes insertion point **334** for the end effector (*e.g.*, needle/catheter module **218**).

[0048] Pseudo skin **220** is disposed adjacent to the inside surface of housing **216** so that it appears to be nearly co-extensive (*i.e.*, co-planar) with housing **216** at openings **330** and **332**. This is intended to create a subtle suggestion that the surface of housing **216** is “skin” at regions other than where pseudo-skin **220** is accessed for skin-interaction techniques. Consistent with human anatomy, the remaining functional elements of haptics device **102** (elements **222** – **228**), with the exception of needle/catheter module **218**, are “hidden” beneath pseudo skin **220**.

[0049] To provide a more realistic simulation of vascular-access procedures, and to provide a realistic feel and haptic feedback to a user during skin-interaction techniques, haptics device **102** includes palpation module **222** and skin-stretch module **224**.

[0050] Palpation module **222** is configured so that when a user presses down on pseudo skin **220** at palpation/occlusion region **331**, the user can feel a vein (*i.e.*, a pseudo vein). In some embodiments, palpation module **222** is capable of simulating the feel of a vein and rendering it with a controllable degree of stiffness (*e.g.*, from not stiff to very stiff) to indicate a degree of engorgement, vein depth, etc. In some further embodiments, palpation module **222** is capable of providing an indication that a palpation technique has, in fact, been conducted. In some other embodiments, palpation module **222** provides a quantitative measure of a user's palpation technique. In some additional embodiments, palpation module **222** enables a user to perform an occlusion technique, and is also capable of monitoring whether the occlusion technique has been performed and, optionally, measuring performance of the technique.

[0051] Skin-stretch module **224** is capable of monitoring skin stretch when a user stretches pseudo skin **220** within skin-stretch region **332**. In some embodiments, skin-stretch module **224** is capable of measuring (*i.e.*, quantifying) the amount of skin stretch.

[0052] The end effector (*e.g.*, needle/catheter module **218**, *etc.*) is inserted into haptics device **102** at insertion point **334** in opening **332**. In some embodiments, simulator **100** is capable of sensing orientation of the end effector, such as to determine the direction the bevel of a needle or catheter. This is an important aspect of the real insertion technique, since proper bevel orientation reduces a patient's discomfort during needle/catheter insertion. In some embodiments, needle/catheter module **218** is configured to be very similar to a real needle and catheter.

[0053] Once inserted into haptics device **102**, the tip of needle/catheter module **218** engages receiver **226**, which, for the illustrative embodiment of a vascular-access simulator, is referred to as a "needle-stick module." Needle-stick module **226** supports the continued "insertion" of the needle/catheter module **218**. In particular, in some embodiments, needle-stick module **226** is configured to provide one linear degree of freedom and two rotational degrees of freedom (*i.e.*, pitch and yaw). The linear degree of freedom provides a variable insertion depth, enabling a user to advance needle/catheter module **218** into the "patient's arm" (*i.e.*, haptics device **102**). The rotational degrees of freedom enable a user to move (an engaged) needle/catheter module **218** up or down and left or right. In some

embodiments, needle-stick module **226** measures insertion depth, and pitch (up/down) and yaw (left/right) angles.

[0054] In some embodiments, needle-stick module **226** provides "force feedback" to a user, whereby the user senses a variable resistance during continued advance (insertion) of needle-stick module **218**. The resistance is intended to simulate penetration of the skin, a vein, and harder structures such as ligaments, bones, and the like. The resistance advantageously varies with insertion depth and the pitch and yaw of needle/catheter module **218**, as described further below.

[0055] It will be understood that the "measurements" of angle, position, etc. that are obtained by the functional elements described above are obtained in conjunction with various sensors and data-processing system **104**. In particular, most of the functional elements described above include one or more sensors. The sensors obtain readings from an associated functional element, wherein the readings are indicative of the rotation, displacement, etc., of the functional element. These readings, therefore, provide information concerning the manipulation of needle/catheter module **218** as well as the performance of palpation, skin-stretch, and occlusion techniques.

[0056] Each sensor then generates a signal that is indicative of the reading, and transmits the signal to electronics/communications interface **228**. Sensors used in some embodiments include, without limitation, potentiometers, encoders, and MEMS devices. Those skilled in the art will know how to use and appropriately select sensors as a function of their intended use in conjunction with the functional elements described above.

[0057] Electronics/communications interface **228** receives the signals transmitted by the various functional elements of haptics device **102** and transmits them to data-processing system **104**. In some embodiments, as an alternative to transmitting the received signals, electronics/communications interface **228** generates new signal(s) based on the received signals, and transmits the new signals to data-processing system **104**. This latter approach requires a substantial increase in processing power and data management (relative to simply transmitting the received signals) and is generally a less-preferred approach. As described later below, electronics/communications interface **228** also receives signals from data processing system **104** and transmits them to needle-stick module **226** as part of a

closed loop force-feedback system. Furthermore, electronics/communications interface **228** distributes power to the various functional modules, as required.

[0058] Data-processing system **104** receives the measurement data and, using the simulation software, calculates the forces that are being applied by the user during the skin-interaction procedures. Furthermore, using an anatomical model, data-processing system **104** calculates the position and angle of a virtual needle within a simulated anatomy (e.g., arm, etc.). Data-processing system **104** displays, on monitor **108**, a rendering of the appropriate anatomy (e.g., arm, etc.) and displays and tracks the course of a virtual needle within this anatomy.

[0056] Furthermore, based on the position and course of the virtual needle (as calculated based on the position and orientation of needle/catheter module **218**), data-processing system **104** generates control signals that are transmitted to needle-stick module **226**. These control signals vary the resistive force presented by needle-stick module **226** to account for various (virtual) anatomical structures (e.g., vein, tissue, tendons, bone, etc.) that needle/catheter module **218** encounters, based on the simulation. As a consequence, the resistance to continued needle/catheter insertion that is experienced by a user of simulator **100** is consistent with the resistance that would be sensed by a practitioner during an actual vascular access procedure.

[0057] Having completed the overview of vascular-access simulator **100** and haptics device **102**, further description of palpation module **222** and skin-stretch module **224** is now provided.

Palpation Module

[0058] Palpation module **222** advantageously provides the following functionality:

- Enables a user to search for a vein.
- Provides haptic feedback to user.
- Provides indirect measurement of palpation force.
- Enables a user to occlude a vein.

[0059] Evaluation of vascular-access procedures and anatomy led to the recognition that, in addition to the listed functionality, it is desirable for palpation module **222** to exhibit certain characteristics, as described below:

- The vein should be felt but not "seen."

- A vein should not be felt when it's not present.
- If pressed hard, the vein should "disappear."
- The vein should have a "spongy" or "yielding" feel when palpated.
- Vein stiffness should be controllable.

[0060] A purpose of palpation during a real vascular-access procedure is to locate a vein that is not visually discernable (e.g., due to advanced age, general health, the depth of the vein, etc.). Consequently, a pseudo vein should not be visually discernable in palpation/occlusion region **331** of haptics device **102**.

[0061] In conjunction with data-processing system **104** and the visual portion of the simulation, in some embodiments, a user "searches" for a vein as a part of the palpation technique. (This is performed using mouse **112**, which moves a rendering of a user's fingers over a rendering of a portion of the human body, e.g., the arm, etc., that appears in monitor **108**, thereby designating a location at which to palpate.) Veins will not be present at all of the user-designated palpation locations. If a vein is not present, as determined by the anatomical model being used in conjunction with data-processing system **104**, a vein should not be tactiley discernable by a user at palpation/occlusion region **331**.

[0062] If a medical practitioner presses hard on a vein, the practitioner will lose the feel of the vein. As a consequence, if a vein has been located, but a user presses too hard in palpation/occlusion region **331**, the feel of the pseudo vein is advantageously lost.

[0063] When palpated, veins have a "spongy" feel; that is, they yield to palpation pressure and do not offer any significant resistive force. It is desirable, therefore, for a user that is palpating a pseudo vein at palpation/occlusion region **331** of haptics device **102** to experience to this sensation of "yielding" or "sponginess."

[0064] The perceived "stiffness" of a vein is related to its degree of engorgement (with blood). An engorged vein will feel relatively stiffer while a less-engorged vein will feel relatively less stiff. Engorgement and perceived stiffness will vary from patient-to-patient, etc. This variation is due to a variety of factors, including the age and general health of the patient, etc. Palpation module **222** is, therefore, advantageously capable of controlling the perceived stiffness of a vein.

[0065] Palpation assembly **436** depicted in FIGs. 4A – 4E, which is an illustrative physical realization of palpation module **222**, possesses all of the

functionality and exhibits all the characteristics listed above. But it is understood that palpation assembly **436** is but one physical realization of palpation module **222**; others are contemplated. And for some applications, such as those in which cost is a consideration, it might be desirable or otherwise necessary to implement palpation module **222** such that it provides only some (one or more) of the functions and exhibits only some (one or more) of the characteristics listed above. Those skilled in the art will be able to build and use such other embodiments of palpation module **222** in light of the present disclosure.

[0066] In accordance with some embodiments of the palpation module **222**, user-applied pressure on a pseudo vein is countered by a controllable, but substantially constant force. In palpation assembly **436**, this force is a magnetic force.

[0067] Palpation assembly **436** is physically configured so that the magnetic force is perceived to be substantially constant over the intended range of movement during palpation. This provides the desired "spongy" or "yielding" sensation when the pseudo vein is palpated. The pseudo vein feels spongy or yielding because there is substantially no perceptible change in force as the pseudo vein is pressed. This is contrasted with some other embodiments in which the force that opposes motion of the pseudo vein is provided by a spring. In such embodiments, as the pseudo vein is palpated, the spring compresses, thereby providing an increasing resistance to motion. As a consequence, a user palpating the pseudo vein would not perceive it as being spongy or yielding, as desired.

[0068] By changing the magnitude of the magnetic force, a greater or lesser (but still substantially constant) force will oppose movement of the pseudo vein. Consequently, a user palpating the pseudo vein will sense "stiffness."

[0069] FIG. 4A depicts an exploded side view of palpation assembly **436**. As shown in that Figure, palpation assembly **436** includes upper plate **438**, lower plate **444**, pseudo vein **446**, coils **450**, permanent magnets **452**, and standoffs **454**, arranged as shown. A top view of lower plate **444** is depicted in FIG. 4B, in which pseudo vein **446** and reflective object sensor **448** are shown. Coils **450**, which are disposed on lower surface of lower plate **444**, are shown in phantom. Also depicted in phantom in FIG. 4B is electrical connection **449**, which places palpation assembly **436** in electrical connection with electronics/communications interface **228**. A top

view of upper plate **438** is depicted in FIG. 4C, in which vein-receiving slot **440** and collar **442** are shown.

[0070] In some embodiments, lower plate **444** is a printed circuit board, which is useful for conducting electrical signals to coils **450**. In other embodiments, lower plate **444** can be made of aluminum or other metals, plastic, or other conveniently available materials. In some embodiments, upper plate **438** is made of aluminum. In embodiments in which the sensor that measures user manipulations of palpation assembly **436** is reflective object sensor **448**, upper plate **438** should be formed from reflective metal or other reflective materials. Alternatively, in some other embodiments, upper plate **438** is formed from a non-reflective material but includes a reflective material at an appropriate location.

[0071] In the illustrative embodiment, pseudo vein **446** is a mock vein. It comprises a solid material, such as aluminum, hard plastic, etc. In other embodiments, an imitation vein can suitably be used. Coils **450** are simply windings of wire that are electrically coupled to a source of current.

[0072] Permanent magnets **452** advantageously comprise materials that exhibit relatively high magnetic field strength for their weight, such as, without limitation, rare-earth magnets. Rare-earth magnets include, for example, neodymium iron boron (NdFeB) and samarium cobalt (SmCo). Rare-earth magnets are commercially available from Magnet Applications, Inc. of Horsham, Pennsylvania, among others. Standoffs **454** are formed of aluminum, stainless, plastic, etc. A variety of spacers, bumpers, and other incidental parts that are typically included and serve to prevent contact between the various elements, provide height adjustment, serve as fasteners, etc., are not depicted in the Figure for the sake of clarity.

[0073] With continuing reference to FIG. 4A, screws **456** pass through upper plate **438**, lower plate **444**, coils **450**, and screw into magnets **452**. Upper plate **438** is stationary, fixed to screws **456** (by nuts, etc., not pictured) while lower plate **444** is not fixed so that it is free to move upward or downward along the screws. Standoffs **454** raise the plates **438** and **444** and pseudo vein **446** within housing **216** to a height that is appropriate for performing palpation at palpation/occlusion region **331**.

[0074] The upper portion of each magnet **452** extends into coils **450**. When coils **450** are energized by the application of current, a magnetic field is generated.

The direction of the current flow is set so that the interaction of the magnetic fields from coils 450 and the upper pole of permanent magnets 452 is repulsive. For this arrangement, the graph of field strength vs. position along the axial direction (of the coil) is an inverted parabola. That is, as coil 452 moves in either direction away from the "upper" poles of magnets 452 (i.e., either "above" magnets 452 or toward the middle of magnets 452), field strength drops. By virtue of this arrangement, palpation assembly 436 is being operated at the relatively flat part of the field strength vs. position curve (i.e., near the maxima). As a consequence, a user senses a substantially "constant" force in opposition to palpation of pseudo vein 446.

[0075] The repulsive force generated between coils 450 and permanent magnets 452 urges lower plate 444 towards upper plate 438. As lower plate 444 moves towards upper plate 438, pseudo vein 446 passes through vein-receiving slot 440 in the upper plate. Urged upwardly by the repulsive magnetic force, lower plate 444 ultimately (nearly) abuts upper plate 438. Contact between the plates is advantageously prevented using thin Teflon® bumpers, etc. (not depicted). In this energized position, which is depicted in FIG. 4D, pseudo vein 446 extends above upper plate 438 and is available for palpation.

[0076] Pseudo skin 220 is advantageously formed of a material that is opaque so that pseudo vein 446 is not visible beneath it. Furthermore, the impression or shape of pseudo vein 446 should not be discernable underneath pseudo skin 220, as would occur if the pseudo vein was in contact with the pseudo skin. To this end, pseudo vein 446 does not extend above collar 442, which supports pseudo skin 220. Collar 442 therefore serves as a stand-off to prevent contact between the pseudo vein and pseudo skin (before palpation). As a consequence, pseudo vein 446 is neither directly nor indirectly visually discernable below pseudo skin 220.

[0077] As a user palpates imitation skin 220 in palpation/occlusion region 331, pseudo vein 446 is felt. The pseudo vein yields to gentle downward pressure by a user, the magnetic repulsion creating the desired "spongy" feel.

[0078] When, according to the simulation, a vein should not be present, pseudo vein 446 retracts to a position that is substantially flush with the upper surface of upper plate 438 (see, FIG. 4E). This is accomplished by reducing current to coils 450, or by simply completely de-energizing the coils, which causes the lower

plate 444 to drop away from upper plate 438. The same result obtains when pseudo vein 446 is palpated (*i.e.*, pressed) with "too" much force by a user.

[0079] In this retracted position, pseudo vein 446 is not tactiley discernable by a user that is attempting a palpation procedure in palpation/occlusion region 331. By virtue of this structural configuration, pseudo vein 446 is flush with the surface of upper plate 438 when the pseudo vein retracts. As a consequence, vein-receiving slot 440 cannot be felt by a user. This is desirable, since vein-receiving slot 440 is not analogous to any anatomical structure within the body.

[0080] The perceived stiffness of pseudo vein 446, which is intended to be an indicator of vein engorgement (with blood), can be altered by adjusting the amount of current to coils 450. For example, with the application of a suitably small amount of current, a repulsive force that just overcomes gravity can be generated. In such a case, the user cannot sense pseudo vein 446 during palpation. With the application of more current, a stronger repulsive force is generated, wherein a user that is palpating pseudo vein 446 is able to sense it. A relatively smaller repulsive force is used to mimic the feel of a vein that is not engorged with blood. A relatively greater repulsive force is used to mimic a stiff, blood-gorged vein. In this fashion, a range of vein stiffness is controllably presented to a user.

[0081] A quantitative measure of a user's palpation technique is obtained in conjunction with the use of a sensor. In the illustrative embodiment, a reflective object sensor 448 is used. As is well known, a reflective object sensor typically consists of an infrared emitting diode and a phototransistor. The phototransistor responds to radiation from the diode only when a reflective object passes within its field of view. One suitable reflective object sensor is a miniature surface mount device no. QRE1113.GR available from Fairchild Semiconductor of South Portland, Maine.

[0082] Since reflective object sensor 448 is disposed on the upper surface of lower plate 444, the diode in sensor 448 responds to radiation reflected from the lower surface of upper plate 438. The reflected radiation is used to determine the distance between lower plate 444 and upper plate 438. This distance is used, in some embodiments, to estimate the amount of force applied by the user during a palpation procedure.

[0083] Palpation assembly 436 also enables a user to perform an occlusion technique, as previously described. In the illustrative embodiment, occlusion is

monitored using pseudo vein **446**. More particularly, as a user applies pressure to pseudo vein **446**, it moves downward along with lower plate **444**. This movement is captured by reflective object sensor **448**. The downward movement is used as an indicator that an occlusion technique has been performed. In some embodiments, to monitor occlusion, the repulsive force generated by coils **450** is adjusted to be just sufficient to overcome gravity. In such a case, the user cannot sense pseudo vein **446**.

Skin-stretch Module

[0084] Skin-stretch module **224** advantageously provides the following functionality and characteristics:

- Enables a user to stretch the skin.
- Provides haptic feedback to user.
- Provides a realistic feel to a user.
- Measures the amount of skin stretch.

[0085] Skin-stretch assembly **558** depicted in FIG. 5A, which is an illustrative physical realization of skin-stretch module **224**, possesses all of the functionality and exhibits all the characteristics listed above. Some other embodiments of skin-stretch module **224** include only some (one or more) of the functionality and characteristics listed above. Those skilled in the art will be able to build and use such other embodiments of palpation module **222** in light of the present disclosure.

[0086] Referring to FIG. 5A, skin-stretch assembly **558** includes platform **560** and linear potentiometer **564**. The linear potentiometer, which is disposed in opening **562** in platform **560**, includes potentiometer slide **566**. Skin-stretch assembly **558** is placed in electrical connection with electronics/communications interface **228** via electrical connection **568**. Linear potentiometer **564** is commercially available from Bourns Co. of Riverside, California and others.

[0087] As depicted in FIG. 5B, skin-stretch assembly **558** is disposed beneath pseudo skin **220** in skin-stretch region **333**. Plate **570**, which is disposed between pseudo skin **220** and slide **566**, is coupled to the slide. The plate is sized so that it extends to edges of skin-stretch region **333**. FIG. 5C depicts thumb **572** of a user applying downward pressure **574** to pseudo skin **220** in the skin-stretch region. This downward pressure forces pseudo skin **220** into contact with plate **570** (not depicted in FIG. 5C). Once in contact with plate **570**, any movement of pseudo skin

220 along the axial direction of potentiometer **564** will cause plate **570** to move, and potentiometer slide **566** to move along with it. FIG. 5D depicts thumb **572** of a user applying a pulling force **576** that stretches pseudo skin **220**. As the pseudo skin stretches, plate **570** (not depicted in FIG. 5D) and potentiometer slide **566** both move, monitoring the stretch. Linear potentiometer **564** generates a signal that is indicate of the amount of skin stretch and transmits it to electronics/communications interface **228** via electrical connection **568**.

[0088] It is to be understood that the above-described embodiments are merely illustrative of the present invention and that many variations of the above-described embodiments can be devised by those skilled in the art without departing from the scope of the invention. For example, in this specification, numerous specific details are provided in order provide a thorough description and understanding of the illustrative embodiments of the present invention. Those skilled in the art will recognize, however, that the invention can be practiced without one or more of those details, or with other methods, materials, components, etc.

[0089] Furthermore, in some instances, well-known structures, materials, or operations are not shown or described in detail to avoid obscuring aspects of the illustrative embodiments. It is understood that the various embodiments shown in the Figures are illustrative, and are not necessarily drawn to scale. Furthermore, the particular features, structures, materials, or characteristics can be combined in any suitable manner in one or more embodiments. It is therefore intended that such variations be included within the scope of the following claims and their equivalents.